

# **EXHIBIT 78**

# DEA Compliance Trip Report – 10/17/13

**Event:** Meeting with DEA Headquarters (Requested by Qualitest)

**Location:** DEA HQ, 600 Army-Navy Drive, Arlington, VA

**Qualitest Attendee(s):** Peter Bigelow, Neil Shusterman and Tracey Hernandez

## **DEA Attendees:**

Cathy Gallagher, Policy & Liaison	Christine Sannerud, Quota & UN Reporting	Erika Gehrmann, Office of Diversion Control
Ruth Carter, Policy & Liaison	Greg Kavanagh, Quota & UN Reporting	Jim Arnold, Regulatory Unit
John Purcell, Policy & Liaison	Stacy Harper-Avilla, Quota & UN Reporting	Patricia Millier, DEA Group Supervisor (Birmingham)

**Summary:** The information we provided was well-received and although no decisions were communicated by DEA at the meeting, it was felt by all Qualitest attendees that the DEA was aligned with our concerns and appreciative to have received the information.

The meeting began with introductions at approximately 1:50 p.m. Discussions occurred as follows:

## **Organizational Changes:**

DEA was provided brief background on Don and Rajiv's prior pharmaceutical experience and their continued commitment to DEA compliance. HQ personnel were made aware of both Rajiv's telephone conversation with our local AL office Group Supervisor and Don's in-person meeting with her last month. DEA was told about changes to our Plant Managers and a brief synopsis of their experience was also provided. They were pleased to hear about the changes in both the DEA Compliance and Security Groups and were happy to hear that responsibility for suspicious order monitoring had moved to DEA Compliance. In addition, they were happy to hear of the addition of Genora Massey as our Manager SOPs & Training.

## **DEA Compliance Investments:**

DEA had several questions about the improvements we are making. They were told about the additional cameras, access upgrades to manufacturing rooms, additional background checks we're requiring, random searches, enhanced contractor procedures, temporary personnel dropping from approximately 150 in 2012 to less than a dozen currently (in production/packaging). They were informed that our scales would be installed by end of year and that over 1000 production and warehouse personnel had been trained in the month of September alone.

Pictures were shown of the Tablets Vault construction and the Charlotte QC Laboratory. DEA was told we were diligently trying to get the vault done by end of year but that it may go a couple of weeks into 2014 (no concerns were expressed). Peter noted that we had built the vault with the capability to quickly expand if hydrocodone were to move to Schedule II. DEA nodded but gave no indication one way or the other of the status of that decision.

Erika G. asked about the buildings in Huntsville and if we had a campus registration. Tracey explained that Pat and she had discussed this but agreed that we needed to have some additional controls in place before we would both be comfortable with that. We explained that we would certainly like to have one at some point in the future. They commented "That's a really nice lab!" at seeing the Charlotte photograph.

**Expansion Plans for Charlotte:**

The two slides for Charlotte were reviewed and DEA was provided information about the current and proposed flow of product and the current and future DEA license plans. It was explained that the facilities were on the same street and were .5 and .2 miles apart. They were told that we use a dedicated Qualitest locked truck and two drivers to transport product. Tracey asked DEA if this was something they would consider for a campus registration. Cathy G. said that wasn't something they could answer at this meeting as they'd have to talk to the local office and some other folks. Tracey asked if they would like us to submit a letter with the two slides we reviewed and an explanation of our plans and Cathy confirmed that they would like that. DEA expressed that they were glad we covered it in person also as it gave them a good understanding of our concerns and what we are considering.

**Removal of High Dose Acetaminophen:**

DEA declined to provide information on their strategy for handling the removal of the high dose acetaminophen products but they clearly understood our position and agreed to work with us early in 2014 if the anticipated volumes materialize. We did express to DEA our worry that if they were to continue to grant quota to the higher dose manufacturers, it would consume our market share. They indicated that if our sales materialize as projected but have not yet made it through IMS, that we should provide sales data alone with our request for this instance.

DEA asked if we knew what pharmacists were planning to do and Peter told them that we're not really sure as we've gotten mixed messages. It did not appear that DEA had had any real conversations with FDA and they were surprised to hear that FDA was meeting to discuss what their actions should be this week. We told DEA that if we hear anything about the outcome of that meeting we would certainly share that with them and would ask that they do the same.

**Suspicious Order Monitoring (SOMs):**

DEA was advised that we took the meeting on March 6<sup>th</sup> very seriously and had heeded their recommendations. We noted we had contracted with Cegedim for the initial evaluation of orders based on volume, frequency & pattern. DEA commented that we should be aware that contracting this work out does not dissolve our responsibility should the Cegedim system not pick up an order of interest. We assured DEA that we understand and that we had several other layers to our SOMS program that we would discuss. We then communicated that we would be placing a maximum quantity boundary on customers so that if the system did not trigger them as an order of interest (because they have historically ordered large quantities), that exceeding this boundary would cause them to be further evaluated. DEA was told that the system would go live November 1<sup>st</sup>. It was communicated that our longer term plan is to discontinue the contract with Cegedim and bring the program in-house (once a new ERP system is put into place).

We spoke about the Manager position and the experience of Eric Brantley, the individual filling the role. We explained to DEA how we felt confident we had put someone with excellent experience in the role to assure the success of the program.

We then talked about the chargeback data and the fact that one year's worth of data equates to about 24M line items. We explained the challenge of not being able to sort through the data as quickly as we would like and told them that although the information is usable, it is very cumbersome and we are looking at dashboard type solutions to gain efficiencies.

Lastly, we discussed customer due diligence visits and the two contracts we had signed. DEA asked who the companies were and we noted Cegedim and PharmaCompliance. We explained that at some point, we would like to handle these audits in house but for the time being these contracts would allow us to institute audits quickly and learn from both companies. DEA liked the approach. We informed them that we would be sending a letter to all customers today (10/18), to notify them of the changes to our program and introduce the DEA team and that next week we plan to send letters to our primary customers regarding the secondary customers of concern that DEA had provided to us. We also communicated that Eric had developed a training program (they were impressed that the training plan included Distribution personnel), and that the training program would be rolled out November 1<sup>st</sup> (inside Sales, Customer Service & Distribution) and 14<sup>th</sup> (Sales reps). They were also informed that we have four SOMS SOPs in draft (set up of new accounts, site visits, cage/vault order review and identifying, blocking & reporting of orders). DEA seemed to be pleased with our progress but really didn't comment one way or the other as to whether or not it was sufficient.

**Presentation of Opana Abuse Data:**

Neil's presentation on Opana ER was well received. DEA asked about next steps with FDA and Neil said that FDA wanted to see longer term data. He indicated that we will continue to gather the information and plan to approach FDA again once the data is available. Interestingly, Kathy G. commented that they had just heard a similar presentation from another pharmaceutical company the day prior.

The meeting ended at approximately 3:20p.m.